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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,220	05/16/2002	Kim King Tong Lau	117-373	6272
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NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714				
			EXAMINER NOGUEROLA, ALEXANDER STEPHAN	
			ART UNIT 1753	PAPER NUMBER

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,220

Applicant(s)

LAU ET AL.

Examiner

ALEX NOGUEROLA

Art Unit

1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-27, 29-31 and 35-39 is/are rejected.
- 7) ☒ Claim(s) 28 and 32-34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 36 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 36 and 37 each require a limitation from a cancelled claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 22-24, 38, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by the CAPLUS abstract of Chen et al. ("Redox electrode for monitoring oxidase-catalyzed reactions," *Clinica Chimica Acta* (1990), 193(3), 187-92). Although only the abstract is currently available to the examiner the index of terms (IT) lists oxidase and glucose determination in blood.

5. Claims 22 and 31 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the CAPLUS abstract of Ikeda et al. ("An efficient method for entrapping ionic mediators in the enzyme layer of mediated amperometric biosensors," *Agricultural and Biological Chemistry* (1988), 52(12), 3187-8).
6. Claim 22 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by the CAPLUS abstract of Yao et al. ("Flow injection analysis for uric acid by the combined use of an immobilized uricase reactor and a peroxidase electrode," *Nippon Kagaku Kaishi* (1985), (2), 189-92) as evidenced by the CAPLUS abstract of Tatsuma et al. "Oxidase/peroxidase bilayer-modified electrodes as sensors for lactate, pyruvate, cholesterol and uric acid," *Analytica Chimica Acta* (1991), 242(1), 85-9) ("Tatsuma"). Tatsuma evidences that hydrogen peroxide is produced by uricase.
7. Claim 22 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by the CAPLUS abstract of Zhdanov et al. ("Amperometric titration of hydrogen peroxide by solutions of some oxidizing agents in an apparatus with a rotating platinum electrode," *Uzbekskii Khimicheskii Zhurnal* (1968, 12(2), 16-18).
8. Claim 22 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by the CAPLUS abstract of Zhdanov et al. ("Amperometric titration of potassium ferricyanide with hydrogen peroxide on an apparatus with a rotating platinum electrode," *Uzbekskii Khimicheskii Zhurnal* (1967), 11(4), 17-19).

9. Claims 22-24, 38, and 39 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the CAPLUS abstract of Blaedel et al. ("Continuous analysis by the amperometric measurement of reaction rate," *Anal. Chem.* (1964), 36(2), 343-7).
10. Claims 22-24, 38, and 39 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Riffer (US 4,552,840). See claim 1; col. 2, ll. 20-49; and col. 4, ll. 31-63.
11. Claims 22, 23, 25-27, 29, 30, 38, and 39 are rejected under 35 U.S.C. 102(a) as being anticipated by Svitel et al. ("Composite biosensor for Sulfite Assay: Use of Water-Insoluble Hexacyanoferrate(III) Salts as Electron-Transfer Mediators," *Electroanalysis* 1998, 10, No. 9) as evidenced by the CAPLUS abstract of Baeza et al. ("The hydrogen ion dependence amperometric detection of H₂O₂ and hexacyanoferrate ions and the pH profiles of immobilized enzyme preparations," *Quimica Analitica* (Barcelona, Spain) (1993), 12(1), 12-17) ("Baeza") and the CAPLUS abstract of Valdes et al. ("Amperometric determination of sulfite and hydrogen peroxide in aqueous solution by flow injection analysis with immobilized sulfite oxidase," *Ingeniera y Ciencia Quimica* (1995), 15(2), 35-8) ("Valdes"). See the abstract of Svitel. Note that hydrogen peroxide is a product of the reaction of sulfite oxidase upon sulfite, as evidenced by Baeza and Valdes.

For the limitations of claim 25 note that although not stated there are three ammonium ions (such as tridodecyltrimethylammonium ions) to balance the charge on $\text{Fe}(\text{CN})_6^{3-}$. See 2.3 Preparation of Water-Insoluble Mediators on page 592.

For the additional limitations of claim 26 see 2.3 Preparation of Water-Insoluble Mediators on page 592.

For the additional limitation of claim 27 see 2.3 Preparation of Water-Insoluble Mediators on page 592 (note at least hexadecyltrimethylammonium also note tetraheptylammonium, which is a homolog of at least tetrahexylammonium).

For the additional limitations of claim 29 and 30 see 2.3 Preparation of Water-Insoluble Mediators on page 592.

12. Claims 22, 25-27, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Figure 3 and the CAPLUS abstract of Shiiki et al. (JP 04070558 A2) ("Shiiki") as evidenced by the alcohol dehydrogenase reaction obtained from www.worthington-iochem.com/ADH/default.html ("ADH"). Note that although Shiiki does not mention hydrogen peroxide, the disclosed sensor is capable of determining the concentration of hydrogen peroxide as it comprises a ferricyanide compound which, in reduced form, functions as a mediator selective for hydrogen peroxide. As seen from ADH alcohol dehydrogenase does not react with hydrogen peroxide so if the sensor is exposed to hydrogen peroxide the ferricyanide compound will react with it.

For the additional limitations of claim 25 note that although not stated there are three ammonium ions (such as hexadecyltrimethylammonium ions) to balance the charge on $\text{Fe}(\text{CN})_6^{3-}$.

For the additional limitations of claim 26 see the Shiiki abstract.

For the additional limitation of claim 27 see the Shiiki abstract (hexadecyltrimethylammonium).

For the additional limitations of claim 35 note “cartridge” 3 in Figure 3 of Shiiki.

13. Claims 22, 25, 26, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Nanba et al. (EP 0400918 A1) (“Nanba”) as evidenced by the alcohol dehydrogenase reaction obtained from www.worthington-biochem.com/ADH/default.html (“ADH”). See Example 20 and claim 1. Note that although Nanba does not mention hydrogen peroxide, the disclosed sensor is capable of determining the concentration of hydrogen peroxide as it comprises a ferricyanide compound which, in reduced form, functions as a mediator selective for hydrogen peroxide. As seen from ADH alcohol dehydrogenase does not react with hydrogen peroxide so if the sensor is exposed to hydrogen peroxide the ferricyanide compound will react with it. Also, claim 13 of Nanba does not specify the enzyme or enzyme type.

For the additional limitations of claim 25 note that although not stated there are three ammonium ions (such as dimethyl di-n-octadecyl ammonium ions) to balance the charge on $\text{Fe}(\text{CN})_6^{3-}$. See col. 8, ll. 26-38 and col. 16, ll. 19-41.

For the additional limitations of claim 26 see col. 8, ll. 26-38 and col. 16, ll. 19-41.

For the additional limitations of claim 26 see col. 8, ll. 26-38

For the additional limitations of claims 29 and 30 see col. 8, ll. 26-38

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Svitel et al. ("Composite biosensor for Sulfite Assay: Use of Water-Insoluble Hexacyanoferrate(III) Salts as

Electron-Transfer Mediators,” *Electroanalysis* 1998, 10, No. 9) (“Svitel”) as evidenced by the CAPLUS abstract of Baeza et al. (“The hydrogen ion dependence amperometric detection of H₂O₂ and hexacyanoferrate ions and the pH profiles of immobilized enzyme preparations,” *Quimica Analitica* (Barcelona, Spain) (1993), 12(1), 12-17) (“Baeza”) and the CAPLUS abstract of Valdes et al. (“Amperometric determination of sulfite and hydrogen peroxide in aqueous solution by flow injection analysis with immobilized sulfite oxidase,” *Ingeniera y Ciencia Quimica* (1995), 15(2), 35-8) (“Valdes”) in view of Negishi et al. (US 5,380,422) (“Negishi”).

Svitel as evidenced by Baeza and Valdes discloses an amperometric sensor as set forth in claim 22. See the rejection above of claim 22 under 35 U.S.C. 102 (a) as being anticipated by Svitel as evidenced by Baeza and Valdes. Svitel as evidenced by Baeza and Valdes does not mention a “cartridge” for the sensor. Negishi discloses a cartridge for a cylindrical tubular working electrode (Figures 1 and 2A), which is the basic structure of the sensor of Svitel (see the last paragraph in the second column on page 592). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a cartridge as taught by Negishi in the invention of Svitel as evidenced by Baeza and Valdes because then a reference electrode or a reference electrode and counter electrode can be compactly associated with the sensor (working electrode) of Svitel in one device.

18. Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riffer (US 4,552,840) (“Riffer”) in view of Turner et al. (US 5,624,537) (“Turner”).

Riffer discloses an amperometric sensor as set forth in claim 22. See the rejection above

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of claim 22 under 35 U.S.C. 102 (b) as being clearly anticipated by Riffer. Riffer does not mention a "cartridge" for the sensor. Turner discloses a cartridge for an electrochemical enzyme sensor. See the abstract; Figure 1; col. 7, ll. 48-60; and col. 18, ll. 8-15. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a cartridge as taught by Turner in the invention of Riffer because then sensor can be mounted in a bioreactor, such as a fermenter for real-time analysis. See col. 5, ll. 4-18 in Turner and col. 1, ll. 5-13 in Riffer.

For claims 36 and 37, assuming that Applicant intended for the enzyme to be as specified in claims 23 and 24, respectively, instead of claims 2 and 3, note that claims 23 and 24 have also been addressed under 35 U.S.C. 102 (b) as being clearly anticipated by Blaedel.

19. Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over the CAPLUS abstract of Blaedel et al. ("Continuous analysis by the amperometric measurement of reaction rate," *Anal. Chem.* (1964), 36(2), 343-7) ("Blaedel").

Blaedel discloses an amperometric sensor as set forth in claim 22. See the rejection above of claim 22 under 35 U.S.C. 102 (b) as being clearly anticipated by Blaedel. Blaedel does not mention a "cartridge" for the sensor; however, assuming that one is not disclosed in the full article It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a cartridge such as a case to protect the sensor from mechanical damage and insulate it from contamination when it is not being used.

For claims 36 and 37, assuming that Applicant intended for the enzyme to be as specified in claims 23 and 24, respectively, instead of claims 2 and 3, note that claims 23 and 24 have also been addressed under 35 U.S.C. 102 (b) as being clearly anticipated by Blaedel.

20. Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over the CAPLUS abstract of Chen et al. ("Redox electrode for monitoring oxidase-catalyzed reactions," *Clinica Chimica Acta* (1990), 193(3), 187-92) ("Chen").

Chen discloses an amperometric sensor as set forth in claim 22. See the rejection above of claim 22 under 35 U.S.C. 102 (b) as being clearly anticipated by Chen. Chen does not mention a "cartridge" for the sensor; however, assuming that one is not disclosed in the full article It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a cartridge such as a case to protect the sensor from mechanical damage and insulate it from contamination when it is not being used.

For claims 36 and 37, assuming that Applicant intended for the enzyme to be as specified in claims 23 and 24, respectively, instead of claims 2 and 3, note that claims 23 and 24 have also been addressed under 35 U.S.C. 102 (b) as being clearly anticipated by Chen.

Allowable Subject Matter

21. Claims 28 and 32-34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

22. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 28: the nonobvious limitation in the combination of limitations is the requirement that "X" be an alkyl substituted phosphonium ion.

In Svitel the "X"'s are alkyl substituted ammonium ions or alkyl substituted pyridinium ions.

In Nanba the "X"'s are alkyl substituted ammonium ions or alkyl substituted pyridinium ions.

In Shiiki the "X" is an alkyl substituted ammonium ion;

b) Claim 32: the nonobvious limitation in the combination of limitations is the requirement that the polymer be a polyacrylamide. In Ikeda the corresponding polymer is DEAE-Sephadex A 50 (which is made from crosslinked dextran. See Data File: Ion exchange chromatography, Sephadex ® ion exchange media by Amersham Biosciences) and poly-L-lysine;

c) Claim 33: the nonobvious limitation in the combination of limitations is the requirement that the ferricyanide compound be bound to the polymer via a group of the specified ammonium ion or the specified phosphonium ion or via a nitrogen-containing heterocyclic cation. In Ikeda the ferricyanide compound is bound via K^+ ; and

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d) Claim 34: the nonobvious limitation in the combination of limitations is the requirement that the ferricyanide compound be polypyridinium ammonium ferricyanide or poly(acrylamide-co-dietyldimethyl ammonium) ferricyanide. In Ikeda the ferricyanide compounds includes K ferricyanide and DEAE Sephadex A 50 (which is made from crosslinked dextran). See Data File: Ion exchange chromatography, Sephadex ® ion exchange media by Amersham Biosciences) or K ferricyanide poly-L-lysine.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Noguerola
Primary Examiner
AU 1753
October 30, 2004